REMARKS

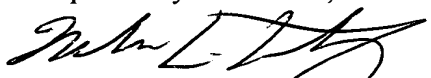
The Office rejected claims 1-32 under 35 U.S.C. § 101 as claiming the same invention as that of claims 1-25 of U.S. Patent No. 6,617,321 B2. The Office further objected to claim 33 as being dependent upon a rejected base claim, but indicated that it would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicants respectfully submit that it appears the claims 1-33 referred to above by the Office are the claims as they stood prior to entry of the preliminary amendment that was filed with the present continuation on July 3, 2003. A copy of the preliminary amendment is attached herewith as is the postcard receipt indicating receipt of the preliminary amendment for the convenience of the Office and for their reference.

Applicants submit that, in fact, claims 1, 3-7, 10-17, 21-24, and 34 are pending in the present continuation application rather than claims 1-33. In addition, Applicants submit that the claims, as amended, specifically relate to olanzapine pamoate monohydrate. In view of the preliminary amendment to the claims, Applicants respectfully assert that rejection of the claims under 35 U.S.C. § 101 is improper.

In view of the above arguments, Applicants submit that claims 1, 3-7, 10-17, 21-24, and 34 are in condition for allowance. Reconsideration and withdrawal of the rejection and objection is respectfully requested and allowance of claims 1, 3-7, 10-17, 21-24, and 34 is kindly solicited.

Respectfully submitted,



Nelsen L. Lentz
Attorney for Applicants
Registration No. 38,537
Phone: 317-276-1207

Eli Lilly and Company
Patent Division/NLL
P.O. Box 6288
Indianapolis, Indiana 46206-6288

December 13, 2004

"Express Mail" mailing label number EL230529738US

Date of Deposit 7-03-03

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. 1.10 on the date indicated above and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

GWEN THOMAS Gwen Thomas

Printed Name Signature

PATENT APPLICATION
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Douglas James Allen et al.)

For: 2-Methyl-Thieno-Benzodiazepine Formulation)

Docket No.: X-11666C)

PRELIMINARY AMENDMENT

Commissioner for Patents
P. O. Box 1450
Arlington, VA 22202-0327
Sir:

Prior to examination of the above-identified application, entry of the following preliminary amendments to the claims and specification, which are attached hereto, is respectfully requested. An Information Disclosure Statement is included herewith.

REMARKS

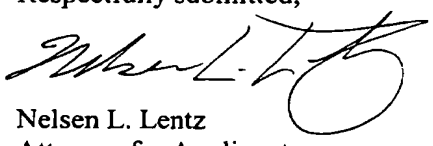
The cross reference in the specification has been amended to indicate that this application is a continuation application of United States Application Serial No. 10/136,887, filed May 1, 2002 which is a continuation application of United States Application Serial No. 09/509,757, filed March 29, 2000 which is a 371 of PCT/US98/20426 filed September 30, 1998 which claims priority to United States Provisional Application Number 60/060,493 filed September 30, 1997. Applicants wish to point out that United States Application Serial No. 10/136,887, filed May 1, 2002, has been allowed.

In addition, the claims have been amended as set forth in the attachment herewith pursuant to 37 C.F.R § 1.121. In particular, claims 2, 8, 9, 18-20, and 25-33 have been

cancelled. Support for the amendment to claim 1 can be found, for example, in original claim 2, and on page 3, lines 19-20. Support for the amendment to claim 4 can be found on page 33, lines 13-16 and page 34, line 32. Support for the amendments to claims 5 and 17 can be found on page 33, lines 13-16. Claim 21 was amended so as to depend upon a noncancelled claim. Support for new claim 34 can be found, for example, on page 2, lines 25-27 and page 3, lines 19-20. It is respectfully submitted that entry of the amendments submitted herewith introduces no new matter to the application.

Applicants respectfully submit that claims 1, 3-7, 10-17, 21-24, and 34 are in condition for examination. An early allowance of claims 1, 3-7, 10-17, 21-24, and 34 is kindly solicited.

Respectfully submitted,



Nelsen L. Lentz
Attorney for Applicants
Registration No. 38,537
Phone: 317-276-1207

Eli Lilly and Company
Patent Division
P. O. Box 6288
Indianapolis, Indiana 46285

June 30, 2003

Amendment to the Specification Pursuant to

37 C.F.R. § 1.121 Revised Format

After the title on page 1, please replace the current cross-reference with the following cross-reference:

--This is a continuation application of United States Application Serial No. 10/136,887, filed May 1, 2002 which is a continuation application of United States Application Serial No. 09/509,757, filed March 29, 2000 which is a 371 of PCT/US98/20426 filed September 30, 1998 which claims priority to United States Provisional Application Number 60/060,493 filed September 30, 1997.--

Amendments to the Claims Pursuant to

37 C.F.R. § 1.121 Revised Format

We claim:

1. (currently amended) A formulation comprising olanzapine pamoate monohydrate ~~olanzapine or a pamoate salt or solvate thereof~~ as an active ingredient and one or more carriers selected from the group consisting of an oleaginous carrier or cholesterol microsphere carrier wherein said formulation has a prolonged sustained release of greater than 7 days and a burst release of less than 15% of the active ingredient.

2. (cancelled)

3. A formulation as claimed in Claim 1 wherein said carrier is oleagenous.

4. (currently amended) A formulation of Claim 1 wherein said carrier is selected from the group consisting of ~~PLURONICS~~ nonionic copolymers of propylene oxide and ethylene oxide, cellulosic, gums, polysaccharide gums, vegetable oils, refined fractionated oils, sucrose diacetate hexaisobutyrate, chitosan, lecithin, and ~~POVIDONE~~ polyvinyl pyrrolidone.

5. (currently amended) A formulation as claimed in Claim 4 wherein said carrier is selected from the group consisting of ~~PLURONICS~~ nonionic copolymers of propylene oxide and ethylene oxide, cellulosic gums, polysaccharide gums, vegetable oils, and refined fractionated oils.

6. (original) A formulation as claimed by Claim 2 wherein the formulation further comprises one or more pharmaceutically acceptable excipients.

7. (original) A formulation as claimed by Claim 6 wherein the pharmaceutically acceptable excipient is selected from the group consisting of a gelling agent and an antihydration agent.

8. (cancelled)

9. (cancelled)

10. (original) A formulation as claimed in Claim 1 wherein the carrier is a cholesterol microparticle.

11. (original) A formulation as claimed in Claim 10 wherein the microparticle is a microsphere.

12. (original) A formulation as claimed in Claim 10 wherein the cholesterol is selected from the group consisting of cholesterol, cholesterol palmitate, cholesterol oleate, cholesterol stearate, and cholesterol hemisuccinate.

13. (original) A formulation as claimed in Claim 10 wherein the microspheres have a particle size of from 20 to 500μm.

14. (original) A formulation as claimed in Claim 13 wherein the particle size is from 30 to 200μm.

15. (original) A formulation as claimed in Claim 14 wherein the particle size is from 40 to 100μm.

16. (original) A formulation as claimed in Claim 10 wherein the microspheres are administered in an oleaginous carrier.

17. (currently amended) A formulation as claimed in Claim 16 wherein the oleaginous carrier is selected from the group consisting of ~~PLURONICS~~ nonionic copolymers of propylene oxide and ethylene oxide, cellulosic gums, polysaccharide gums, vegetable oils, and refined fractionated oils.

18-20. (cancelled)

21. (currently amended) A formulation as claimed in claim 1 ~~Claim 20~~ wherein the active ingredient is milled.

22. (original) A formulation as claimed in Claim 21 wherein the particle size is from 20 to 60μm.

23. (original) A formulation as claimed in Claim 22 wherein the particle size is from 5 to 20μm.

24. (original) A formulation as claimed in Claim 23 wherein the milled particles are less than or equal to 5μm.

25-33. (cancelled)

34. (new) A formulation comprising olanzapine pamoate monohydrate as an active ingredient, and one or more carriers.

Amendments to the Claims Pursuant to
37 C.F.R. § 1.121 Revised Format

We claim:

1. (currently amended) A formulation comprising olanzapine pamoate monohydrate ~~olanzapine or a pamoate salt or solvate thereof~~ as an active ingredient and one or more carriers selected from the group consisting of an oleaginous carrier or cholesterol microsphere carrier wherein said formulation has a prolonged sustained release of greater than 7 days and a burst release of less than 15% of the active ingredient.

2. (cancelled)

3. A formulation as claimed in Claim 1 wherein said carrier is oleagenous.

4. (currently amended) A formulation of Claim 1 wherein said carrier is selected from the group consisting of ~~PLURONICS~~ nonionic copolymers of propylene oxide and ethylene oxide, cellulosic, gums, polysaccharide gums, vegetable oils, refined fractionated oils, sucrose diacetate hexaisobutyrate, chitosan, lecithin, and ~~POVIDONE~~ polyvinyl pyrrolidone.

5. (currently amended) A formulation as claimed in Claim 4 wherein said carrier is selected from the group consisting of ~~PLURONICS~~ nonionic copolymers of propylene oxide and ethylene oxide, cellulosic gums, polysaccharide gums, vegetable oils, and refined fractionated oils.

6. (original) A formulation as claimed by Claim 2 wherein the formulation further comprises one or more pharmaceutically acceptable excipients.

7. (original) A formulation as claimed by Claim 6 wherein the pharmaceutically acceptable excipient is selected from the group consisting of a gelling agent and an antihydration agent.

8. (cancelled)

9. (cancelled)

10. (original) A formulation as claimed in Claim 1 wherein the carrier is a cholesterol microparticle.

11. (original) A formulation as claimed in Claim 10 wherein the microparticle is a microsphere.

12. (original) A formulation as claimed in Claim 10 wherein the cholesterol is selected from the group consisting of cholesterol, cholesterol palmitate, cholesterol oleate, cholesterol stearate, and cholesterol hemisuccinate.

13. (original) A formulation as claimed in Claim 10 wherein the microspheres have a particle size of from 20 to 500μm.

14. (original) A formulation as claimed in Claim 13 wherein the particle size is from 30 to 200μm.

15. (original) A formulation as claimed in Claim 14 wherein the particle size is from 40 to 100μm.

16. (original) A formulation as claimed in Claim 10 wherein the microspheres are administered in an oleaginous carrier.

17. (currently amended) A formulation as claimed in Claim 16 wherein the oleaginous carrier is selected from the group consisting of ~~PLURONICS~~ nonionic copolymers of propylene oxide and ethylene oxide, cellulosic gums, polysaccharide gums, vegetable oils, and refined fractionated oils.

18-20. (cancelled)

21. (currently amended) A formulation as claimed in claim 1 ~~Claim 20~~ wherein the active ingredient is milled.

22. (original) A formulation as claimed in Claim 21 wherein the particle size is from 20 to 60μm.

23. (original) A formulation as claimed in Claim 22 wherein the particle size is from 5 to 20μm.

24. (original) A formulation as claimed in Claim 23 wherein the milled particles are less than or equal to 5μm.

25-33. (cancelled)

34. (new) A formulation comprising olanzapine pamoate monohydrate as an active ingredient, and one or more carriers.

PATENT Dkt No. X-11666C Atty NLL

RECEIVED BY THE UNITED STATES PATENT & TRADEMARK OFFICE:

Org ____, CIP ____, Div ____, Con ✓, Prov ____, PCT Nat'l ____, CPA ____
Application of: Douglas James Allen, et al.
Titled: 2-Methyl-Thieno-Benzodiazepine Formulation
Consisting of Fee Transmittal, Utility Patent Transmittal and
Claims, Abstract, Specification (68 pages), Drawings (____ sheets)
Declaration and Power of Attorney ____ National Phase Declaration ✓
Preliminary Amendment ✓ Stmt 821 ____: Diskette ____
Recordation/Assignment ____ IDS/1449 ✓
Miscellaneous Papers:

21904 U.S. PTO
10/613619
07/03/03

Express Mail Label No. EL230529738US